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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,009	05/13/2005	Pieter De Haan	O-2002.745 US	3638

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INTERVET INC.
PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966-0318

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/535,009	DE HAAN ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/13/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/535,009 filed on 05/13/2005. Claims 1-10 are pending and are presented for examination on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of quotation marks around the word wrap brings ambiguity to the word wrap. For purposes of examination, the Examiner will examine the claims as if the quotation marks were not present.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by De Haan et al. (WO 98/47517).

Instant claim 1 is drawn to: A stabilized pharmaceutical tablet comprising an amount of from 0.1 to 10% by weight of tibolone provided with a coating.

Instant claim 2 is drawn to: A tablet according to claim 1 wherein the coating is a film coating, a sugar coating, a sugar film coating or a "wrap" coating.

De Haan et al. disclose a pharmaceutical dosage unit comprising tibolone in an amount of from 0.1 to 10% by weight, and a pharmaceutically acceptable carrier (Claim 1). De Haan et al. disclose that the tablets can be provided with a film coat (Page 5, lines 14-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Haan et al. (WO 98/47517) in view of Small et al. (US 3,751,277).

De Haan et al. is discussed above and that discussion is hereby incorporated by reference.

De Haan et al. do not expressly disclose a tablet coating wherein the coating is a sugar coating or a sugar film coating wherein the sugar comprises sucrose and wherein

the coating contains a plasticizer selected from the group consisting of glycerin, propylene glycol, and polyethylene glycol.

De Haan et al. do not expressly disclose a method of stabilizing a pharmaceutical tablet comprising an amount of from 0.1 to 10% by weight of tibolone comprising applying a coating to the tablet wherein the coating is a film coating, a sugar coating, a sugar film coating or a wrap coating wherein the coating is a sugar coating or a sugar film coating wherein the sugar comprises sucrose.

Small et al. teach a composition for coating tablets comprising a sugar, sucrose, and plasticizer, propylene glycol, and methods of coating tablets (Claims 1-3 and 8). Glycerin is also mentioned as part of the coating composition and method in claims 1 and 8.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to coat the composition of De Haan et al. with the coating composition and methods of Small et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Small et al. disclose that the composition is soluble in water and can be rapidly applied with spraying or automated procedures and have a particular advantage in coating tablets prepared with binders such as ethyl cellulose and for tablets containing active ingredients which are reactive with organic solvents (Column 1, line 67- column 2, lines 1-2 and column 9, lines 15-23).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Claim Rejections - 35 USC § 103

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Haan et al. (WO 98/47517) in view of Lech et al. (US 5,641,513).

De Haan et al. is discussed above and that discussion is hereby incorporated by reference.

De Haan et al. do not expressly disclose a tablet coating wherein the coating is a sugar coating or a sugar film coating wherein the sugar comprises sucrose and wherein the coating contains a plasticizer selected from the group consisting of glycerin, propylene glycol, and polyethylene glycol.

Lech et al. teach a composition for use in coating pharmaceutical tablets comprising sucrose, cellulose ethers such as methyl cellulose and hydroxypropylcellulsoe and a plasticizer such as glycerin or polyethylene glycol (Column 4, lines 17-63 and claims 1-4).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to coat the composition of De Haan et al. with the coating composition of Lech et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Lech et al. disclose that the composition dissolves rapidly in water to form a dispersion of the polymer coating ingredients and such rapid dissolution allows for increased processing rates (Abstract).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Claim Rejections - 35 USC § 103

Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Haan et al. (WO 98/47517) in view of Lech et al. (US 5,641,536).

De Haan et al. is discussed above and that discussion is hereby incorporated by reference.

De Haan et al. do not expressly disclose a method of stabilizing a pharmaceutical tablet comprising an amount of from 0.1 to 10% by weight of tibolone comprising applying a coating to the tablet wherein the coating is a film coating, a sugar coating, a sugar film coating or a wrap coating wherein the coating is a sugar coating or a sugar film coating wherein the sugar comprises sucrose.

Lech et al. teach methods for coating pharmaceutical tablets comprising a composition comprising saccharides such as sucrose, cellulose ethers such as methyl cellulose and plasticizers such as glycerin and propylene glycol (Column 4, lines 20-65 and claims 1-7).

One of ordinary skill in the art would have been motivated to do this because Lech et al. disclose that the composition dissolves rapidly in water to form a dispersion of the polymer coating ingredients and such rapid dissolution allows for increased processing rates (Abstract).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,512,556; EP 0613687; EP 0389035 and WO 00/23460 teach process of making and pharmaceutical compositions comprising (7α, 15α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA

JOHN PAK
PRIMARY EXAMINER
GROUP 1600